UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

MEMORANDUM

12/16/2020

SUBJECT: Acute Toxicity Review for *Fabric Treated with Livinguard® Technology*, EPA File Symbol 95700-E; DP 459602; A540

FROM: Wallace Powell
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Jenny J. Tao, Senior Scientist (Acute Toxicology) 12/16/2020
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Joseph Varco, PM Team 33 / Zebora Johnson
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: Livinguard, AG		
Decision No.: 564512	Submission No.: 1054331	E-Sub No.: 52336
MRIDs (Submitted): 51206101 through 51206106		

PC code	Active Ingredient	% weight
107401	3-(Trimethoxysilyl) Propyldimethyloctadecyl ammonium chloride	0.59
111801	Poly(hexamethylene biguanide hydrochloride) (PHMB)	0.23
072501	Silver	0.16
122101	Propiconazole	0.40
	Other Ingredients	98.62
	Total	100.00

I. BACKGROUND

In support of registration for the proposed product, *Fabric Treated with Livinguard® Technology*, EPA File Symbol 95700-E, the registrant has submitted studies for acute dermal toxicity, skin irritation, and dermal sensitization. In addition, waivers have been requested for acute oral toxicity, acute inhalation toxicity, and eye irritation. The submitted MRIDs are listed in the table below. Reviews of the studies are attached to this memorandum. The proposed product is an antimicrobial pesticide-treated fabric product that is intended to be used in healthcare and laboratories, hospitality and cruise ships, and food processing, handling and packaging settings.

II. RECOMMENDATION

2.1 The submitted acute dermal toxicity, dermal irritation, and dermal sensitization studies are acceptable in support of the Toxicity Categories listed in the table below.

2.2 The acute oral and acute inhalation toxicity and eye irritation waiver requests are acceptable, in accordance with the Agency waiver guidance issued on March 1, 2012 and the physical state of the proposed product.

2.3 The acute toxicity profile for *Fabric Treated with Livinguard® Technology*, EPA File Symbol 95700-E, is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	51206103	---	Waived
Acute Dermal Toxicity	51206104	IV	Acceptable
Acute Inhalation Toxicity	51206101	---	Waived
Primary Eye Irritation	51206102	---	Waived
Primary Dermal Irritation	51206105	IV	Acceptable
Dermal Sensitization	51206106	Non-sensitizer	Acceptable

Conclusion: The acute toxicity data requirements have been met to support the registration of EPA File Symbol 95700-E.

III. PRODUCT LABELING

Based on the above acute toxicity profile for the subject product, no specific First Aid or human-hazard precautionary statements (or headings) are required except the front-panel precaution "Keep Out of Reach of Children" (KOROC). The Agency Risk Management Product Manager (PM) may, in accordance with 40 CFR §156.66, decide whether to waive the KOROC requirement, and whether to approve its placement on other than the front panel. The presence of a signal word is optional. If a signal word is used, it must be "CAUTION" and should appear immediately below the front-panel statement "Keep Out of Reach of Children".

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OCSPP 870.1200)

Reviewer: J. Tao
MRID No.: 51206104
Study No.: 45331
Study Completion Date: 06/07/2017

Testing Laboratory: Product Safety Labs
Author: C. Lowe

Quality Assurance (40 CFR §160): Included

Test Material: Livinguard Lot 6; Lot#: EPA LOT 6; Ceil blue fabric
Dose Levels: 5000 mg/kg of body weights

Species: Rat, Sprague-Dawley
Sex: 5 males and 5 Females
Age: 10-11 weeks
Weight: Males: 280-348 grams; Females: 146-240 grams
Source: SAGE® Labs

Summary:

1. **Estimated LD_{50}**: >5000 mg/kg
2. **Toxicity Category**: IV
3. **Classification**: Acceptable-Guideline

Procedure comments and/or Guideline 870.1200 deviations: None.

Method: The test substance was a fabric which was cut into pieces and weighed to the actual size amount of 5000 mg/kg of body weight. The appropriate amount of test substance was applied to a 2 inch x 3 inch (approx. 10% of the total body surface), 4-ply gauze pad moistened with approximately 0.5 mL of distilled water and placed on the dose area for 24 hours. The day of application was considered Day 0 of the study. The animals were observed for mortality, signs of gross toxicity, and behavioral changes at least once daily for 14 days. Body weights were recorded prior to application (initial and again on Days 7 and 14 (terminal)). Necropsies were performed on all animals at terminal sacrifice.

Results: There was no mortality. All animals gained weight and appeared active and healthy during the 14 days of observation. There were no signs of adverse clinical effects, dermal irritation, or abnormal behavior. No abnormal gross findings were noted for any of the animals when necropsied at the end of the 14-day observation period.

Reported Mortality			
Dose Level (mg/kg)	**Males**	**Females**	**Total**
5000	0/5	0/5	0/10

DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OCSPP 870.2500)

Reviewer: J. Tao
MRID No.: 51206105
Report No.: 45332
Study Completion Date: 06/07/2017

Testing Laboratory: Product Safety Labs
Author: C. Lowe

Quality Assurance (40 CFR §160): Included

Test Material: Livinguard Lot 6; Lot#: EPA LOT 6; Ceil blue fabric
Dosage: Four 1-inch x 1-inch square pieces of the test substance totaling at least 0.5 grams

Animals: Rabbit, New Zealand albino
Sex: 3 Female
Age: 11 weeks
Weight: 2734-2876 g
Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable-Guideline

Procedure comments and/or Guideline 870.2500 deviations: None noted

Method: The test substance was a fabric and was cut into 1-inch x 1-inch square pieces. Four 1-inch x 1-inch square pieces of the test substance totaling at least 0.5 grams were moistened with distilled water and then applied to one 6-cm^2 skin on each animal for 4 hours. After 4 hours of exposure, the dose sites were gently cleansed with a 3% soap solution followed by tap water and a clean paper towel to remove any residual test substance. The dermal irritation was evaluated by the Draize method of scoring.

Results:
The table below provides the individual Draize scores from four-hour dermal exposures of three female rabbits to the test material applied to intact clipped application sites measuring 6.0 cm^2. There was no skin irritation observed at any treated site during the study.

Individual Dermal Irritation Scores following the four-hour exposure

ERYTHEMA/EDEMA

Animal No.	Sex	Time After Patch Removal			
		30-60 min	24hrs	48 hrs	72 hrs
3504	F	0/0	0/0	0/0	0/0
3505	F	0/0	0/0	0/0	0/0
3506	F	0/0	0/0	0/0	0/0
Total		0/0	0/0	0/0	0/0
Mean		0/0	0/0	0/0	0/0

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (OCSPP 870.2600)

Reviewer: J. Tao
MRID No.: 51206106
Report No.: 45333
Study Completion Date: 06/07/2017

Testing Laboratory: Product Safety Labs
Author: C. Lowe

Quality Assurance (40 CFR §160): Included

Test Substance: Livinguard Lot 6; Lot#: EPA LOT 6; Ceil blue fabric
Positive Control Material: α-Hexylcinnamaldehyde, ≥ 95% (HCA)

Species: Guinea pigs/Hartley albino, male
Weight: 502-885 grams (test and control groups)
Age: Not stated
Source: Hilltop Lab Animals, Inc.

Method: Buehler Method

Summary:

1. Livinguard Lot 6 is ***not*** a contact sensitizer.
2. **Classification**: Acceptable-Guideline

Procedure comments and/or Guideline 870.2600 deviations: None noted

Results:

The table below summarizes the incidence and severity of the sensitization response noted after challenge. Based on the test results, the test substance (20-22 mm fabric circles moistened with 0.1 mL of distilled water) is not considered to be a contact sensitizer. The Positive Control group tested positive, as appropriate.

No clinical signs of toxicity were noted in control or test group animals. All animals survived to study termination and gained weight.

	Sensitization Response Indices			
	Incidence of Positive Response[1]		Severity[2]	
	Hours		Hours	
	24	48	24	48
Test Animals	0/20	0/20	0	0
Naive Control Animals	0/10	0/10	0	0

[1] Animals with scores greater than 0.5.
[2] Sum of the erythema scores divided by the number of animals evaluated.